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APPLICATION NO.	FILIN	NG DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/634,679 08/04/2003		04/2003	Silvia Corvera	07917-171001 / UMMC 02-41	7172		
26161	7590	01/24/2006		EXAM	EXAMINER		
FISH & RIC	CHARDSO	N PC	MITRA	MITRA, RITA			
P.O. BOX 10 MINNEAPO		55440-1022	ART UNIT	PAPER NUMBER			
			1653				

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applicati	on No.	Applicant(s)						
	055 4-4 0	10/634,6	79	CORVERA ET AL.						
	Office Action Summary	Examine	r	Art Unit						
		Rita Mitra		1653						
Period fo	The MAILING DATE of this communication a or Reply	ppears on th	e cover sheet with the c	orrespondence ac	ddress					
WHIC - Exte after - If NC - Failt Any	CORTENED STATUTORY PERIOD FOR REF CHEVER IS LONGER, FROM THE MAILING insions of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication. O period for reply is specified above, the maximum statutory perious are to reply within the set or extended period for reply will, by state reply received by the Office later than three months after the mailed patent term adjustment. See 37 CFR 1.704(b).	DATE OF TI 1.136(a). In no ev od will apply and w ute, cause the app	HIS COMMUNICATION rent, however, may a reply be tim rill expire SIX (6) MONTHS from blication to become ABANDONE	N. nely filed the mailing date of this c D (35 U.S.C. § 133).						
Status										
1) 又	Responsive to communication(s) filed on 09	November 2	005.							
	This action is FINAL . 2b)⊠ This action is non-final.									
3)	Since this application is in condition for allow	ance except	for formal matters, pro	secution as to the	e merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.									
Disposit	ion of Claims									
5) 6) 7)	Claim(s) 1-47 is/are pending in the application 4a) Of the above claim(s) is/are withded Claim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) is/are objected to. Claim(s) 1-47 are subject to restriction and/or	rawn from co								
Applicat	ion Papers									
9)[The specification is objected to by the Exami	ner.								
10)	10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.									
	Applicant may not request that any objection to the	ne drawing(s) l	e held in abeyance. See	e 37 CFR 1.85(a).						
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).									
11)	The oath or declaration is objected to by the	Examiner. No	ote the attached Office	Action or form P1	ΓΟ-152.					
Priority ι	under 35 U.S.C. § 119									
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 										
Attachmen			A) 🗖 Jatoniau Suura	(DTO 442)						
2) 🔲 Notic 3) 🔲 Infor	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/0 r No(s)/Mail Date	8)	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	te	O-152)					

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DETAILED ACTION

Applicants' Response to Restriction Requirements filed on November 9, 2005 is acknowledged. Applicants have elected without traverse Group I, claims 1-19. Upon further consideration restriction requirement in office action of September 7, 2005 is withdrawn in view of not considering some claims that required further restriction. Therefore, claims 1-47 are currently under examination.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I Claims 1-19, drawn to an isolated lipid binding domain, comprising an amino acid sequence of SEQ ID NO: 1; a lipid binding molecule comprising said lipid binding domain and a reporter group linked to it; classified in class 530, subclass 300, 350, 359.

The claims in Group I contain reference to patentably distinct and/or independent peptides, see claims 1, 2, 3, 4, 5, 9 and 10 for each of X, U and J in SEQ ID NO: 1. Should Group I be elected, applicant is required to select one residue to define the X, U and J in the sequence of SEQ ID NO: 1 in claims 1-5, 9 and 10; select one sequence from claim 9; and select one reporter group from claim 17. Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide. Because the peptides are considered patentably distinct, **this is not a species election**.

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Group II

Claims 20-27, drawn to a method for detecting a lipid within a lipid bilayer in a sample, comprising a) obtaining a lipid binding molecule of claim 11, b) mixing the lipid binding molecule with the sample to form a complex and detecting the complex; classified in class 530, subclass 300, 350, 359.

The claims in Group II contain reference to patentably distinct and/or independent peptides, see claim 1 for each of X, U and J in SEQ ID NO: 1. Should Group II be elected, applicant is required to select one residue to define the sequence of SEQ ID NO: 1 in claim 1. Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide. Because the peptides are considered patentably distinct, this is not a species election.

Group III

Claims 28-35, drawn to a method for locating a lipid-containing cellular organelle within a cell, comprising a) obtaining a lipid binding molecule of claim 11, b) entering the lipid binding molecule to the cell, c) detecting the reporter group of the lipid binding molecule; classified in class 530, subclass 300, 350, 359; class 435, subclass 7.1

The claims in Group III contain reference to patentably distinct and/or independent peptides, see claim 1 for each of X, U and J in SEQ ID NO: 1.

Should Group III be elected, applicant is required to select one residue to define the sequence of SEQ ID NO: 1 in claim 1. Any change of amino acid residue at

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any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide. Because the peptides are considered patentably distinct, this is not a species election.

Group IV

Claims 36-40, drawn to a method for diagnosing a subject for infection by a microorganism, comprising a) obtaining a cell from the subject, b) binding a lipid binding molecule of claim 11 to a phagosome in the cell, c) detecting the reporter group on the phagosome, d) determining whether the phagosome is capable of fusing to a lysosome; classified in class 530, subclass 300, 350, 359; class 435, subclass 7.1

The claims in Group IV contain reference to patentably distinct and/or independent peptides, see claim 1 for each of X, U and J in SEQ ID NO: 1. Should Group IV be elected, applicant is required to select one residue to define the sequence of SEQ ID NO: 1 in claim 1. Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide. Because the peptides are considered patentably distinct, this is not a species election.

Group V

Claims 41-47, drawn to a method for determining whether a test compound is a candidate compound for treating *Mycobacterium tuberculosis*, comprising, a) binding a lipid binding molecule of claim 11 to a phagosome in a cell infected by *Mycobacterium tuberculosis*, b) applying a test compound to the infected cell, c)

visualizing the phagosome before and after application of the test compound; classified in class 530, subclass 300, 350, 359; class 435, subclass 7.1

The claims in Group V contain reference to patentably distinct and/or independent peptides, see claim 1 for each of X, U and J in SEQ ID NO: 1. Should Group V be elected, applicant is required to select one residue to define the sequence of SEQ ID NO: 1 in claim 1. Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide. Because the peptides are considered patentably distinct, this is not a species election.

Inventions in Group I and Groups II/III/IV/V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP '806.05(h)). In the instant case the claimed lipid binding domain of Group I can be used as a lipid binding agent in a materially different process other than those of Groups II, III, IV and V. Therefore, the inventions are patentably distinct.

Inventions in Group II, III, IV and V are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP '806.04, MPEP '808.01). In the instant case the inventions are distinct each from the other, because they require different steps and are directed to different ends and different effect. Therefore, the inventions are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a

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separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the

Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita Mitra, Ph.D.

January 18, 2006

JONWEBER

SUPERVISORY PATENT EXAMINER

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